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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,145	08/22/2003	Bong Cheol Kim	2540.0020001/TJS/M-N	8727

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
01/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,145	KIM ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *146-148,150-177,179-203,233 and 237-244* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *146-148,150-177,179-203,233 and 237-244* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed September 23, 2009 presents remarks and arguments submitted to the office action mailed June 23, 2009 is acknowledged.

Applicant's arguments over the 35 U.S.C. 112 first rejection of claims 146, 149-176, 178-203, 204, and 207-232 is persuasive in view of the amendment made to the claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 146-148, 150-153, 155-177, 179-183, 185-203, 233,237-244 unpatentable over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A), and Tsuboi et al. (JP 02202808 A), Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A) is not persuasive. Therefore, the rejection is maintained for reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 154 and 184 unpatentable over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A) and Tsuboi et al. (JP 02202808 A), Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A), as applied to claims 146-148, 150-153, 155-177, 179-183, 185-203, 233,237-244, and further in view of Suzuki et al.

(US 20020054923 A1) is not persuasive. Therefore, the rejection is maintained for reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 146-148, 150-153, 155-177, 179-183, 185-203, 233,237-244 unpatentable over Forastiere et al. ("Consumption of fresh fruit rich in vitamin C and wheezing symptoms in children", Thorax 2000, 55: 283-288), cited by the Applicant, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A) and further in view of Lee et al. (Oral Administration of IL-12 Suppresses Anaphylactic Reactions in a Murine Model of Peanut Hypersensitivity Clinical Immunology Vol. 101, No. 2, November, pp. 220–228, 2001) and Wei (US 5177060 A) is persuasive in view of the amendment made to the claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 154 and 184 unpatentable over Forastiere et al. ("Consumption of fresh fruit rich in vitamin C and wheezing symptoms in children", Thorax 2000, 55: 283-288), cited by the Applicant, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A) and further in view of Lee et al. (Oral Administration of IL-12 Suppresses Anaphylactic Reactions in a Murine Model of Peanut Hypersensitivity Clinical Immunology Vol. 101, No. 2, November, pp. 220–228, 2001) and Wei (US 5177060 A) as applied to claims 146-148, 150-153, 155-177, 179-183, 185-203, 233,237-244, and further in view of Suzuki et al. (US 20020054923 A1) is persuasive in view of the amendment made to the claims. Therefore, the rejection is herewith withdrawn.

The following rejections are restated below and the new rejection is made in view of the IDS.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 146-148, 150-153, 155-177, 179-183, 185-203, 233,237-244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A), and Tsuboi et al. (JP 02202808 A), Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A).

Murad teaches a method of treating dermatological disorders, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwi fruit extract. See col. 8, lines 10-29. The fruit extract is present in an amount of 0.01-80 wt. %. See col. 8, lines 13-16. Murad teaches the same amounts of the extract. The dermatological agent may be administered orally or topically (col 6 line 30).

While broadly teaching "kiwi fruit", Murad does not explicitly teach the claimed species of kiwi fruit nor the extraction process.

However, Endres et al., Udagawa, and Luo et al. show that extracts of the claimed species of kiwi fruit are known in the art and used in cosmetics and pharmaceuticals. See respective Abstracts. Udagawa teaches "The kiwi fruit solution also can be used as a starting material for food (see abstract)."

Additionally, Tsuboi et al. teaches an oral or topical composition of kiwi extract comprising administering two times amount of water is added to kiwi fruit after heat treatment. The fruit is crushed, filtered, and then ethanol is added to same amount of resultant crude solution. The solution is stirred, then aged by leaving at rest in cooling place for a whole day and night, preferably 2-3 days, and filtered by filter paper, with concentrating as necessary (abstract). The amount ethanol used ranges from 0-80%. Tsuboi et al. teaches the kiwi extract has excellent solubility in water system.

Wuthrich is solely used to show that atopic dermatis is associated with an increase in IgE production.

Lukacs et al. is solely used to show that in treating inflammatory disease results in a decrease in the production of Th2-type antibody isotypes, such as IgG1 and IgE, and/or an increase in the production of Th1-type antibody isotypes, such as IgG2a or IgG3.

Capetola et al. is solely used to show the relationship between atopic dermatitis and histamine release and edema.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use *Actinidia arguta, Actinidia kolomikta or Actinidia polygama* and the extraction method of Tsuboi et al. The

motivation to use the *Actinidia arguta, Actinidia kolomikta or Actinidia polygama* of Endres et al., Udagawa, and Luo et al. and the extraction method of Tsuboi et al. for compositions of Murad is because all are kiwi extracts useful in oral compositions and Tsuboi et al. teaches the kiwi extract has excellent solubility in water system. Therefore, the skilled artisan would reasonable expectation of achieving the desired therapeutic results. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 154 and 184 as being unpatentable over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A) and Tsuboi et al. (JP 02202808 A), Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A), as applied to claims 146-148, 150-153, 155-177, 179-183, 185-203, 233,237-244, and further in view of Suzuki et al. (US 20020054923 A1).

Murad is as discussed above.

Murad fails to teach the non-polar solvent ethyl acetate.

Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use the non-polar solvent ethyl acetate. The motivation to use the solvent ethyl acetate of Suzuki et al. for compositions of Murad is because Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like. Therefore, the skilled artisan would reasonable expectation of achieving the desired therapeutic results.

Claims 146-148, 150-153, 155-177, 179-183, 185-203, 233,237-244 are rejected under 35 U.S.C. 103(a) as being unpatentable Motohashi, N., "Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS in view of Tsuboi et al. (JP 02202808 A), Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A).

Motohashi teach the use of Actinidia for the treatment of inflammatory conditions, dermatitis, and edema. The Actinidia can be used in foods. The general disclosure of dermatitis and inflammatory conditions renders obvious the treatment of atopic dermatitis.

Murad does not teach the extraction process.

Tsuboi et al. teaches an oral or topical composition of kiwi extract comprising administering two times amount of water is added to kiwi fruit after heat treatment. The

fruit is crushed, filtered, and then ethanol is added to same amount of resultant crude solution. The solution is stirred, then aged by leaving at rest in cooling place for a whole day and night, preferably 2-3 days, and filtered by filter paper, with concentrating as necessary (abstract). The amount ethanol used ranges from 0-80%. Tsuboi et al. teaches the kiwi extract has excellent solubility in water system.

Wuthrich is solely used to show that atopic dermatis is associated with an increase in IgE production.

Lukacs et al. is solely used to show that in treating inflammatory disease results in a decrease in the production of Th2-type antibody isotypes, such as IgG1 and IgE, and/or an increase in the production of Th1-type antibody isotypes, such as IgG2a or IgG3.

Capetola et al. is solely used to show the relationship between atopic dermatitis and histamine release and edema.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use the extraction method of Tsuboi et al. The motivation to use the the extraction method of Tsuboi et al. for compositions of Motohashi is because Tsuboi et al. teaches the kiwi extract has excellent solubility in water system. Therefore, the skilled artisan would reasonable expectation of achieving the desired therapeutic results.

Claims 154, and 184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motohashi, N., "Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops

Association, Australia (1991) – IDS in view of Tsuboi et al. (JP 02202808 A), Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A), as applied to claims 146-148, 150-153, 155-177, 179-183, 185-203, 233,237-244 and further in view of Suzuki et al. (US 20020054923 A1).

Motohashi is as discussed above.

Motohashi fails to teach the non-polar solvent ethyl acetate.

Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use the non-polar solvent ethyl acetate. The motivation to use the solvent ethyl acetate of Suzuki et al. for compositions of Motohashi is because Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like. Therefore, the skilled artisan would reasonable expectation of achieving the desired therapeutic results.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed September 23, 2009 have been fully considered. The response to the arguments is as discussed below:

Applicant repasts similar arguments made in the previous action. The examiner states the arguement that Murad compositions are not used in treatment of allergic diseases or non-allergic non-dermatological inflammatory diseases is not persuasive. Examiner's contention is that Murad in fact teaches a method of treating dermatological disorders, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwi fruit extract. See col. 8, lines 10-29. Inflammatory dermatoses encompasses the limitation atopic dermatitis.

Applicant argues the Examiner erred in determining the content of Endres reference. More specifically, the Applicant states the Enderes reference fails to teach allergic diseases. The Examiner states that Endres teaches the hardy kiwi juice is used in treating psoriasis an allergic inflammatory disease (also see Pegg et al. US 5955463 A col 11 lines 20-25).

The argument that Udagawa is not useful for oral administration is not persuasive. Udagawa teaches "The kiwi fruit solution also can be used as a starting material for food (see abstract)."

With respect to the argument regarding Lukacs et al. and the production of Th2-type antibody isotypes, such as IgG1 and IgE, and/or an increase in the production of Th1-type antibody isotypes, such as IgG2a or IgG3, the Examiner states: The

inflammatory diseases taught by Lukacs et al. include allergic airway diseases, hyper-eosinophilic syndrome, helminthic parasitic infection, allergic rhinitis, allergic conjunctivitis, dermatitis, eczema, contact dermatitis, or food allergy. Hence, a skilled artisan would know from the teaching of Lukacs that the diseases claimed would in fact modify the production of Th2-type antibody isotypes, such as IgG1 and IgE, and/or an increase in the production of Th1-type antibody isotypes, such as IgG2a or IgG3.

The arguments are not persuasive and the rejection is made **FINAL**.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627